

## Illinois Department of Healthcare and Family Services

### External Defibrillator Prior Approval Criteria

#### Program Rationale

In 2010 the overall rate of death attributable to cardiovascular death (CVD) was 235.5 per 100,000. This is >2,150 Americans with CVD every day that equates to 1 death every 40 seconds. About 150,000 Americans with CVD in 2010 were <65 years of age. Coronary heart disease caused approximately 1 of every 6 deaths in the United States in 2010.<sup>1</sup> Each year approximately 300,000 persons in the United States experience an out-of-hospital cardiac arrest (OHCA) with approximately 92% of those persons expiring. Whereas some of these events are from non-cardiac causes, the majority (70-85%) of such events have a cardiac cause.<sup>2</sup> Many of these OHCA are sudden and unanticipated primarily due to ventricular fibrillation with ventricular tachycardia and bradyarrhythmias also described. Early defibrillation during the first minute of the onset increases the chance of survival to 97% compared to 15-40% for defibrillation at minutes 4-5 dropping to only 5% survival for interventions at 10 minutes or more after the incident. Even with a bystander trained in cardiopulmonary resuscitation (CPR) nearby, it easily takes 1 minute to confirm the circulatory arrest and then initiate a call to emergency medical services. It thereafter takes on average 2 ½ minutes for trained responders to be sent to the scene.<sup>2</sup> However, the majority of OHCA do not receive bystander-assisted cardiopulmonary resuscitation or other timely interventions known to improve survival. Risk stratification for sudden cardiac death considering multiple variables can assist to identify those patients who are at increased risk of sudden cardiac death and decrease that risk by making available external defibrillators.<sup>3</sup>

The defibrillator is intended to minimize that risk while additional work-up is being completed, response to interventions/optimized medical therapy is determined, or serves as a bridge to an implantable cardioverter defibrillator (ICD) implantation/re-implantation or cardiac transplantation. Multiple variables influence arrhythmic death and total mortality risk that need to be considered in addition to ejection fraction.<sup>4</sup> Criteria for approval of a defibrillator are established to attempt to identify those patients who are at high risk for sudden cardiac death due to an arrhythmia.

There are two types of automatic external defibrillators for individual use. One is a **wearable cardioverter defibrillator (K0606)** and the other is a **stand-alone model (E0617)**. These devices are considered for patients who are at high risk for sudden cardiac death due to an arrhythmia for whom an ICD is not presently implanted.

## General Information

1. Requests for both types of automatic external defibrillators require submission of an [HFS 1409 Prior Approval Request form](#).
2. For the K0606, a copy of a signed and dated form [HFS 2305L \(N-2-15\) Informed Consent for Future LifeVest Rental Related to Compliance With Cumulative Wear Time](#) as a contingency for future rental must be submitted at the time the initial prior approval request is received. If this is not submitted with the initial prior approval request, it will be returned as invalid.
3. The ordering physician should be a cardiologist.
4. If the device has already been dispensed, that date must be declared or a copy of the signed and dated delivery receipt must be submitted with the initial request.
5. Documents useful to assess the patient's clinical status and necessity for one of these devices include but are not limited to the following and should be submitted with the prior approval request:
  - a. Admission history and physical;
  - b. Discharge summary;
  - c. Operative reports (coronary artery bypass grafting and ICD implantation / extraction);
  - d. Cardiac catheterization reports (diagnostic and percutaneous coronary intervention);
  - e. Consultative reports from cardiologist, electrophysiologist, and cardiovascular surgeon.
6. Diagnostic testing to assess cardiac function can include the following and should be submitted with the prior approval:
  - a. Transthoracic and transesophageal echocardiography;
  - b. Magnetic resonance imaging;
  - c. Computed tomography;
  - d. Radionuclide angiography (multi-gated acquisition scan);
  - e. Single-photon emission computed tomography;
  - f. Positron emission tomography;
  - g. Cardiac catheterization;
  - h. Electrocardiograms (ECG's), Holter monitors, and genetic testing.
7. Ejection fractions can be measured by angiography, radionuclide scanning, or echocardiography.
8. ECG's and Holter monitor reports are important for conduction disturbances that prompt recommendation for a defibrillator as are test results for genetic conditions associated with potentially life threatening arrhythmias.\*

9. If a prior approval request is received for continued rental of an external defibrillator garment type following a previously approved rental period, updated clinical information about the status of the patient including the treatment plan and updated assessments of cardiac function must be submitted to establish ongoing medical necessity. Approval cannot be based upon the provider's assumption of need.
10. In the unusual event after a wearable cardioverter defibrillator has reached rent to purchase, or for an automatic external defibrillator as applicable:
  - a. A replacement battery (K0607) for the automated external defibrillator, garment type does not require prior approval provided no more than 1 is requested every 365 days and the battery is out of warranty and will not hold a charge.
  - b. A replacement garment (K0608) for the automatic external defibrillator, garment type does not require prior approval provided no more than 1 is requested every 365 days and the garment is not repairable and is out of warranty.
  - c. When quantity limits over the specified times in 10.a. and 10.b. are exceeded, prior approval is required and an explanation must be provided to justify the request.
  - d. Replacement electrodes for either type defibrillator do require prior approval and provided rent to purchase has been reached for the wearable defibrillator. The electrodes must be out of warranty, broken, and damaged beyond repair.

### **HCPCS Code K0606**

K0606 is an automatic external defibrillator with integrated ECG analysis garment type (wearable cardioverter defibrillator). At the present time there is only one manufacturer, ZOLL, of this device, called the LifeVest.<sup>®</sup>

K0606 is a daily rent to purchase item and is almost never an outright purchase item as many of these patients only need this device short term because of improvement in cardiac function in response to interventions and optimized medical therapies or eventually become a recipient of an ICD before 300 days of rent to purchase are reached. At 300 days of rental, the patient owns the defibrillator vest.

The first rental period is usually 30-90 days to thereafter establish what transpired with the patient to allow time for additional work-up and follow-up studies to be completed, to determine response to interventions and optimized medical therapies before approving additional rental. Rental periods bridge to the next decision point in particular as it relates to determination of improvement in cardiac function, implantation of an ICD, or becoming a recipient of a heart transplant following the aforementioned.<sup>5</sup> Individually approved rental periods should not exceed 90 days.

The daily rental includes delivery, all instruction on proper use of the device, maintenance, repair costs, all wearable and non-wearable parts and components, all necessary supplies, and compliance downloads. These items cannot be separately billed during the rental period.

The external defibrillator garment type has the capability to perform compliance downloads. Compliance downloads in the form of bar graphs with accompanying data must be submitted for the entire previously approved rental period upon receipt of all subsequent prior approval requests for additional rental. A cumulative wear time percentage will be calculated over the entire most recently approved prior rental period. The Department requires documentation of a cumulative wear time of 90% or more during the most recently approved entire previous rental period as a contingency to consider subsequent requests for rental. Unless there are extenuating circumstances affecting wear time such as hospitalization, chest wall trauma, or shingles on the chest wall documented by a physician, **failure to meet this 90% requirement will result in denial of a request for continued rental. If compliance data are not provided to the Department, any request for continued rental will be denied. If incomplete compliance data are submitted to the Department for any time periods, the Department will assume the device was not worn during the undocumented period in arriving at this calculation.**

The vest size for the garment type automatic external defibrillator is determined by measuring the chest circumference at the level of the xiphoid just below the breast. The size ranges from 26-56 inches.

An automatic wearable defibrillator with integrated ECG analysis (K0606) can be approved if one of the following criteria is met:

- A. A documented episode of ventricular fibrillation or a sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia (with or without cardiac arrest). These dysrhythmias may be either spontaneous or induced during an electrophysiologic study, but may not be due to a transient or reversible cause\*\* and not occur during the first 48 hours of an acute myocardial infarction, during the first 72 hours post coronary bypass, or within 5 days of a cardiac transplant; **or**
- B. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmias;\* **or**
- C. Either documented prior myocardial infarction or dilated cardiomyopathy and a measured left ventricular ejection fraction (LVEF) less than or equal to 0.35; **or**
- D. Implantation of an ICD is planned; **or**
- E. Meets criteria for ICD implantation but is contraindicated; **or**
- F. A previously implanted defibrillator requires explantation due to infection, lead fracture, battery depletion, manufacturer's recall, device failure, or change in the patient's condition necessitating a different type of device as examples; **or**
- G. Patient has been approved and is on a waiting list for heart transplant, or the member is in phase 2 of the heart transplant process.

An automatic wearable defibrillator with integrated ECG analysis garment type (K0606) will **not** be approved if the patient has any of the following:<sup>6</sup>

- A. Currently has an implantable ICD;
- B. Currently has an external defibrillator;
- C. Hearing, vision, developmental or psychiatric disorder that may prevent interpreting device messages and compliant use of the device;
- D. Taking medications that may impair proper responses to device alarms;
- E. Is unwilling or unable to wear the device continuously except when bathing or showering;
- F. Failure to meet 90% or greater threshold for cumulative wear time over a most recent previously approved rental period at time of receipt of additional request for rental;
- G. Any terminal illness, other than cardiac disease (e.g. cancer, end stage renal disease, liver failure) that clearly and severely limits patient's life expectancy to less than 1 year.
- H. Less than 18 years old;
- I. Exposure to excessive electromagnetic interference (EMI) from machinery such as powerful electric motors, radio transmitters, power lines, or electronic security scanners that can prevent the device from detecting an abnormal heart rhythm;
- J. Of childbearing age and not attempting to prevent pregnancy;
- K. Is pregnant or breast-feeding.

### **HCPCS Code E0617**

E0617 is an external defibrillator with integrated ECG analysis and is a purchase item. The authorized allowable for E0617 includes delivery, all instruction on proper use of the device, and initial supplies necessary to use the defibrillator.

A non-wearable automatic defibrillator (E0617) can be approved in two circumstances. The patient must satisfy both criteria A and B, **or** criteria C as described below and is not a candidate for a wearable cardioverter defibrillator, for example, due to obesity, young age, or size:

- A. The patient must have one of the following conditions (1-7):
  - 1. A documented episode of cardiac arrest due to ventricular fibrillation, not due to a transient or reversible cause;\*\* **or**
  - 2. A sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia, either spontaneous or induced during an electrophysiologic study, not occur during the first 48 hours of an acute myocardial infarction, during the first 72 hours post coronary bypass, or within 5 days of a cardiac transplant, and not due to a transient or reversible cause;\*\* **or**
  - 3. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmias;\* **or**
  - 4. Coronary artery disease with a documented prior myocardial infarction, with an LVEF less than or equal to 0.35, and inducible, sustained ventricular

tachycardia or ventricular fibrillation during an electrophysiologic study. To meet this criterion:

- a. The myocardial infarction must have occurred more than 4 weeks prior to the external defibrillator prescription; **and**
  - b. The electrophysiologic test must have been performed more than 4 weeks after the qualifying myocardial infarction; **or**
5. Documented prior myocardial infarction and a left ventricular ejection fraction less than or equal to 0.30. Patients must not have:
- a. Cardiogenic shock\*\*\* or symptomatic hypotension while in a stable baseline rhythm; **or**
  - b. Clinical symptoms or findings that would make them a candidate for coronary revascularization; **or**
6. Patients with ischemic dilated cardiomyopathy, documented with or without prior myocardial infarction, at least New York Heart Association (NYHA) Class II heart failure, and LVEF less than or equal to 0.35; **or**
7. Patients with nonischemic dilated cardiomyopathy, at least NYHA Class II heart failure, and LVEF less than or equal to 0.35.

B. ICD implantation surgery is contraindicated.

C. A previously implanted defibrillator now requires explantation and the patient is not a candidate for a wearable cardioverter defibrillator.

A non-wearable automatic external defibrillator (E0617) will **not** be approved if the patient has any of the following:

- A. Currently has an implantable ICD;
- B. Currently has an automatic external defibrillator with integrated ECG analysis garment type;
- C. Lacks a live-in caregiver who is available 24 hours per day to promptly and correctly use the device and who has been instructed in cardiopulmonary resuscitation;
- D. Any terminal illness, other than cardiac disease (e.g. cancer, end stage renal disease, liver failure) that clearly and severely limits patient's life expectancy to less than 1 year.

\*Long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia, Brugada syndrome, arrhythmogenic right ventricular dysplasia, hypertrophic cardiomyopathy, or familial dilated cardiomyopathy<sup>7</sup>

\*\*Transient or reversible causes include but are not limited to drug toxicity, severe hypoxia, acidosis, systemic infection, and abnormal blood levels of potassium, calcium, and magnesium.

\*\*\*Clinical criteria for cardiogenic shock are:

Systolic blood pressure (BP) less than 90 mm Hg for at least 30 minutes; **or**

Supportive measures required to maintain systolic BP greater than or equal to 90 mm Hg; **and**

End organ hypoperfusion (cool extremities or urine output less than 30 mls/hr and a heart rate greater than or equal to 60 beats per minute); **or**

Hemodynamic criteria of cardiac index less than or equal to 2.2 L/min per square meter of body surface area and a pulmonary capillary wedge pressure of at least 15 mm Hg.

## References

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6. U.S. Food and Drug Administration LIFECOR Wearable Cardioverter defibrillator (WCD) 2000 System-P010030. Available at <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm083949.htm>
7. Taylor Matthew RG, Carniel Elisa, Mestroni Luisa. Cardiomyopathy, Familial Dilated. Orphanet Journal of Rare Diseases. 2006; 1:27. Available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1559590/>